K073505

5. 510(k) Summary

Contact: Adam Herder
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

Device Trade Name: Valeo™ VBR

JAN - 9 2008

Manufacturer: Amedica Corp.
615 Arapeen Drive, Suite 302
Salt Lake City, UT 84108

Common Name: Spinal intervertebral body fixation orthosis

Classification: 21 CFR §888.3060

Class: II

Product Code: MQP

Indications For Use:

The Valeo™ VBR is intended for vertebral body replacement to aid in surgical correction and stabilization of the spine. The device is indicated for use in the thoracolumbar spine (T1 to L5) to replace or restore height a collapsed, damaged, diseased, or unstable vertebral body or portion thereof, excised as a result of tumor or trauma (i.e., fracture). It is indicated to achieve decompression of the spinal cord and neural tissues, and to restore the height of a collapsed or damaged vertebral body.

The Valeo™ VBR is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. The Valeo™ VBR is always to be used with supplemental internal spinal fixation. Additionally, the Valeo™ VBR may be used with bone graft.

Device Description:

The Valeo™ VBR acts as a spacer to maintain proper vertebral body spacing and angulation following partial or total corpectomy. The Valeo™ VBR is manufactured from MC^2, a ceramic material. The Valeo™ VBR is for single level anterior spinal use from T1-L5.

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Predicate Device(s):

The Valeo™ VBR was shown to be substantially equivalent to the Amedica Valeo™ VBR System cleared in K073125 and the ARX Spinal System cleared in K051525.

Performance Standards:

Testing performed indicates that the Valeo™ VBR is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2008

Amedica Corp.
% Musculoskeletal Clinical & Regulatory Advisers, LLC
Mr. Adam Herder
1331 H Street NW, 12th Floor
Washington, DC 20005

Re: K073505
Trade/Device Name: Valco™ VBR
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: December 11, 2007
Received: December 13, 2007

Dear Mr. Herder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

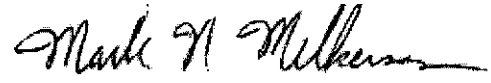
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K073505

Device Name: Amedica Valeo™ VBR

The Valeo™ VBR is intended for vertebral body replacement to aid in surgical correction and stabilization of the spine. The device is indicated for use in the thoracolumbar spine (T1 to L5) to replace or restore height a collapsed, damaged, diseased, or unstable vertebral body or portion thereof, excised as a result of tumor or trauma (i.e., fracture). It is indicated to achieve decompression of the spinal cord and neural tissues, and to restore the height of a collapsed or damaged vertebral body.

The Valeo™ VBR is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. The Valeo™ VBR is always to be used with supplemental internal spinal fixation. Additionally, the Valeo™ VBR may be used with bone graft.

Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073505